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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,973	06/22/2001	Richard M. Kris	NEOGEN-1 WO P2-C2	5288

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EXAMINER	
SPIEGLER, ALEXANDER H	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,973	KRIS ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *11-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/24/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, filed on December 30, 2004, is acknowledged.

Applicants' argue "(t)he examiner has not established that an undue search and burden will be necessary to examine the full scope of the claims." (See Applicants' response to restriction requirement).

This argument has been considered, but is not persuasive for the following reasons. For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation by either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. In the instant case, the serious burden of search has been established by, at least, the different classification of the inventions. (See restriction requirement mailed on August 25, 2003). Furthermore, the inventions are directed to methods having different method steps, starting materials, and goals. Specifically, the combination of Group II is not used in the methods of Group I; Group I comprises subjecting a sample to nuclease protection, whereas nuclease protection is not mentioned in Group II. Thus, Groups I and II are unrelated as each Group is not capable of use together and have different modes of operation, different functions, or different effects.

Accordingly, the restriction requirement is MAINTAINED.

Status of the Application

2. Currently, claims 1-15 are pending, Claims 1-10 are rejected herein and Claims 11-15 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821. This action is made NON-FINAL.

Sequence Notes

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Furthermore, the specification should be amended to insert the appropriate sequence identifying (SEQ ID NO) following each recited sequence. (See pages 73-78).

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION IN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 – 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six-month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Priority

4. If applicant desires priority under 35 U.S.C. 119(e), 120, 121 or 365(c) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (**whether patented or abandoned**) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior

application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Information Disclosure Statement

5. The information disclosure statement filed on July 24, 2001, complies with CFR 1.97, 1.98, and M.P.E.P. 609, and has been considered (see enclosed signed PTO-1449).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-10 recite the limitations "the hybridized duplex molecules" and "the single stranded protected nucleic acid(s)". There is insufficient antecedent basis for these limitations in the claims.

B) Claims 1-10 are indefinite because claim 1 is drawn to a method for detecting one or more nucleic acids of interest, however, the final step is for detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragments. The claims do not set forth the relationship between detecting the nucleic acid of interest and detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragments. Therefore, it is not clear as to whether the claims are intended to be limited to a method of detecting the nucleic acid of interest or a method of detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragments.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> ((e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldrick et al. (USPN 5,422,241).

Goldrick teaches a method to detect one or more nucleic acids of interest, comprising subjecting a sample comprising said nucleic acid(s) to nuclease protection with one or more protection fragments, and detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragment(s). (See cols. 2-4, 6, 8-13 and 18-21). Goldrick teaches the method is a high throughput method, the protection fragments are nucleic acids, a plurality of detection fragments can be detected, the nucleic acid of interest can be measured, the protection fragment is measured, and that the protection fragment is modified chemically. (See cols. 2-4, 6, 8-13 and 18-21).

10. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Stanley et al. (GB 2285445).

Stanley teaches a method to detect one or more nucleic acids of interest, comprising subjecting a sample comprising said nucleic acid(s) to nuclease protection with one or more protection fragments, and detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragment(s). (See abstract and pages 2-4, 6, 9-14 and 16-21). Stanley teaches the method is a high throughput method, the protection fragments are nucleic acids, a plurality of detection fragments can be detected, the nucleic acid of interest can be measured, the protection fragment is measured, and that the protection fragment is modified chemically. (See abstract and pages 2-4, 6, 9-14 and 16-21).

11. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kumar et al. (USPN 5,770,370).

Kumar teaches a method to detect one or more nucleic acids of interest, comprising

subjecting a sample comprising said nucleic acid(s) to nuclease protection with one or more protection fragments, and detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragment(s). (See abstract, Figure 1, and cols. 1, 3, 5, 8-9 and 11-14). Kumar teaches the method is a high throughput method, the protection fragments are nucleic acids, a plurality of detection fragments can be detected, the nucleic acid of interest can be measured, the protection fragment is measured, and that the protection fragment is modified chemically. (See cols. 1-6 and 8-9).

12. Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Balch et al. (USPN 6,083,763, cited in the IDS).

Balch teaches a method to detect one or more nucleic acids of interest, comprising subjecting a sample comprising said nucleic acid(s) to nuclease protection with one or more protection fragments, and detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragment(s). (See Figures 13-14 and Example III, cols. 33-36). Balch teaches the method is a high throughput method, the protection fragments are nucleic acids, a plurality of detection fragments can be detected, the nucleic acid of interest can be measured, the protection fragment is measured, and that the protection fragment is modified chemically. (See Figures 13-14 and Example III, cols. 33-36).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,232,066. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '066 patent are a species of the presently claimed genus.

For example, Claim 1 of the instant case is drawn to:

A method to detect one or more nucleic acids of interest, comprising subjecting a sample comprising said nucleic acid(s) to nuclease protection with one or more protection fragments, and detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragment(s).

Whereas, Claim 1 of the '066 patent is drawn to:

A method of detecting at least one nucleic acid target, comprising contacting a sample which may comprise said target(s) with a nuclease protection fragment(s) specific for and which binds to said target(s), exposing the sample to a nuclease effective to digest remaining single strand nucleic acid, and then contacting the resultant sample with a combination which comprises, before the addition of said sample,

i) a surface comprising multiple spatially discrete regions, at least two of which are substantially identical, each region comprising

ii) at least two different anchors, each in association with

iii) a bifunctional linker which has a first portion that is specific for the anchor, and a second portion that comprises a probe which is specific for said nuclease protection fragment(s),

under conditions effective for said nuclease protection fragment(s) to bind to said combination,

and detecting said bound protection fragment(s).

15. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,238,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '869 patent are a species of the presently claimed genus.

For example, Claim 1 of the instant case is drawn to:

A method to detect one or more nucleic acids of interest, comprising subjecting a sample comprising said nucleic acid(s) to nuclease protection with one or more protection fragments, and detecting the hybridized duplex molecules, or the single strand protected nucleic acid(s), or the protection fragment(s).

Whereas, Claim 1 of the '869 patent is drawn to:

A method of detecting at least one nucleic acid target, comprising

a) contacting a sample which may comprise said target(s) with a nuclease protection fragment(s) specific for and which binds to said target(s), exposing the sample to a nuclease effective to digest remaining single strand nucleic acid, and then contacting the resultant sample with a combination which comprises, before the addition of said sample,

i) a surface, comprising multiple spatially discrete regions, at least two of which are substantially identical, each region comprising

ii) at least two different anchors, each in association with

iii) a bifunctional linker which has a first portion that is specific for the anchor, and a second portion that comprises a probe which is specific for said nuclease protection fragment(s),

under conditions effective for said nuclease protection fragment(s) to bind to said combination,

b) contacting said combination and any bound nuclease protection fragment(s) with at least one detection linker, which comprises a first moiety specific for one of said bound nuclease protection fragment(s) and a second moiety specific for a reporter reagent, and

c) detecting said detection linker(s).

16. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/662,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '749 application are a species of the presently claimed genus, and therefore, the claims of '749 are obvious over the instant claims. Specifically, the claims of '749 require the detection be carried out by mass spectrometry, whereas the present claims are drawn to any detection method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/681,208. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '208 application are a species of the presently claimed genus, and therefore, the claims of '208 are obvious over the instant claims.

Specifically, the claims of '208 require the detection be carried out by mass spectrometry, whereas the present claims are drawn to any detection method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No Claims are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander H. Spiegler
April 2, 2004

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
4/2/04

Notice to Comply	Application No.	Applicant(s)	
	09/885,973	KRIS ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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